



[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Expert Panel Meeting on Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid; Notice of Public Meeting and Registration Information

**SUMMARY:** The National Toxicology Program (NTP) and the Office of Dietary Supplements (ODS) announce a public expert panel meeting on May 11–12, 2015, to identify research needs based on the state of the science related to the safe use of high intakes of folic acid. The expert panel meeting is open to the public. Registration is requested for public attendance, in-person or via the webcast, and for oral comment. Information about the meeting and registration are available at <http://ntp.niehs.nih.gov/go/730864>.

#### DATES:

**Meeting:** May 11–12, 2015, 8:30 a.m. Eastern Daylight Time to approximately 5 p.m. on May 11 and approximately 12:00 p.m. on May 12.

**Document Availability:** The literature review document should be available by April 6, 2015, and will be posted to <http://ntp.niehs.nih.gov/go/730864> when available.

**Written Public Comment Submission and Registration for Oral Comments:** Deadline is May 4, 2015.

Registration for Accommodation: Deadline is May 4, 2015, for individuals with disabilities who need accommodation to participate.

#### ADDRESSES:

Meeting Location: Natcher Conference Center (Building 45), National Institutes of Health, Bethesda, MD 20892.

Meeting Webpage: The preliminary agenda, registration, roster, literature review document, and other meeting materials will be posted to <http://ntp.niehs.nih.gov/go/730864> when available.

Webcast: The URL for viewing the webcast will be provided to those who register.

FOR FURTHER INFORMATION CONTACT: Dr. Yun Xie, NTP Designated Federal Official, Office of Liaison, Policy and Review, DNTP, NIEHS, P.O. Box 12233, MD K2-03, Research Triangle Park, NC 27709. Phone: (919) 541-3436, Fax: (301) 451-5455, Email: [yun.xie@nih.gov](mailto:yun.xie@nih.gov). Hand Delivery/Courier: 530 Davis Drive, Room 2161, Morrisville, NC 27560.

#### SUPPLEMENTARY INFORMATION:

**Meeting and Registration:** The meeting is open to the public with time set aside for oral public comment; attendance at NIH is limited only by the space available. Registration is recommended for in-person attendance to ensure space and to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to provide oral comments (see below) are encouraged to register online by May 4, 2015, at <http://ntp.niehs.nih.gov/go/730864>. Individuals interested in this meeting are encouraged to

access the website to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in-person is available at <http://www.nih.gov/about/visitor/>. Individuals with disabilities who need accommodation to participate in this event should contact Dr. Yun Xie at phone: (919) 541-3436 or email: [yun.xie@nih.gov](mailto:yun.xie@nih.gov). TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

**Background Information on Folic Acid and Reason for the Evaluation:** Humans require folate, a water-soluble B-complex vitamin, for everyday growth and cell division and for critical periods of rapid growth and cell division such as embryonic development. Thus, folate is necessary for all individuals, but is especially important for women who may become pregnant. At the same time, there is interest in understanding potential adverse health impacts from high intakes of folic acid, the form of folate commonly added to foods and dietary supplements.

Folate is present in the diet through its natural occurrence in food, as a food additive, and as an ingredient in dietary supplements. Naturally occurring folate is unlikely to be associated with potential adverse effects because it has lower bioavailability than folic acid and its consumption is also limited by the bulk and caloric content of foods. Therefore, the primary substance of interest for considering the safety of high intake is folic acid.

Evaluating the potential for adverse health effects associated with high folic acid intakes has been challenging because of the lack of systematic studies and other sources of evidence on this topic. In 1998, the Food and Nutrition Board of the Institute of Medicine set Dietary Reference Intakes that included the Recommended Dietary Allowances (RDAs) and tolerable upper intake levels (ULs)—the highest level of daily intake likely to pose no risk of adverse

health effects to almost all of the population—for folic acid and other B vitamins. The folic acid UL (1000 µg) was established with the paucity of data available to the committee at the time; i.e., limited, suggestive evidence that excessive folate intake may precipitate or exacerbate neuropathy in vitamin B12-deficient individuals. Since this 1998 publication that set the UL for folic acid, many publications have reported on health effects over a range of folic acid intakes. Some studies have raised concerns that high intake of folic acid may be associated with potential adverse health effects.

**Expert Panel Meeting:** The NTP and ODS are convening an expert panel to identify research needs related to the safe use of high intakes of folic acid based on consideration of the state of the science. The expert panel meeting will bring together experts from multiple disciplines including, but not limited to, epidemiology, nutrition, medicine, and toxicology. In preparation for this evaluation, screening of the literature was undertaken to identify potential adverse health effects for which further research might be warranted. A literature review document is being prepared on four health outcome areas using systematic review methodology: (1) cancer, (2) cognition in conjunction with vitamin B12, (3) hypersensitivity-related outcomes, and (4) endocrine and metabolic outcomes. The literature review document should be available by April 6, 2015, and will be posted to <http://ntp.niehs.nih.gov/go/730864>. A document describing the approach for conducting the literature evaluation has also been prepared and is posted on the NTP Website ([http://ntp.niehs.nih.gov/ntp/ohat/folicacid/ntpfoliacid\\_approach\\_508.pdf](http://ntp.niehs.nih.gov/ntp/ohat/folicacid/ntpfoliacid_approach_508.pdf)). This document describing the approach includes information on the dose levels of folic acid being considered for the evaluation.

**Request for Comments:** The deadline for submission of written comments is May 4, 2015, to

enable review by the expert panel and NTP and ODS staff prior to the meeting. Registration to provide oral comments is by May 4, 2015, at <http://ntp.niehs.nih.gov/go/730864>. Public comments and any other correspondence should be sent to the FOR FURTHER INFORMATION CONTACT. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and/or sponsoring organization.

Public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the agenda topics. In addition to in-person oral comments at the NIH, public comments can be presented by teleconference line. There will be 50 lines for this call; availability is on a first-come, first-served basis. Oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Each affiliation or sponsoring organization is allowed one time slot. At least 7 minutes will be allotted to each time slot, and if time permits, may be extended to 10 minutes at the discretion of the chair. Persons wishing to make an oral presentation are asked to register online at <http://ntp.niehs.nih.gov/go/730864> by May 4, 2015, and indicate whether they will present comments in-person or via the teleconference line. If possible, oral public commenters should send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for in-person oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for registered speakers and will be determined by the number of speakers who register on-site.

**Background Information on NTP and ODS:** The NTP is an interagency program, established in 1978 (43 FR 53060) and headquartered at the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). The mission of NTP is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP carries out literature analysis activities in the Office of Health Assessment and Translation and the Office of the Reports on Carcinogens. The NTP also designs and conducts laboratory studies and testing programs and analyzes its findings to assess potential hazards to human health from exposure to environmental substances, including dietary supplements (see <http://ntp.niehs.nih.gov/>).

The mission of the ODS of the NIH is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the population of the United States. The purpose and responsibilities of the ODS are to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions; to conduct and coordinate scientific research within NIH relating to dietary supplements; to collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources; and to serve as the principal advisor to the Secretary of the Department of Health and Human Services and the Assistant Secretary for Health and to provide advice on issues relating to dietary supplements to the Director of NIH, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food

and Drug Administration (see <http://ods.od.nih.gov/>). The Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417, DSHEA) authorized the establishment of the ODS at the NIH in 1995.

**Background Information on NTP Expert Panels:** NTP panels are technical, scientific advisory bodies established on an "as needed" basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide current curriculum vitae to the  
FOR FURTHER INFORMATION CONTACT. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: December 2, 2014.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2014-28681 Filed 12/05/2014 at 8:45 am; Publication Date: 12/08/2014]